



Substitute for Form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 3

Complete if Known

Application Number	10/571,311
Filing Date	March 9, 2006
First Named Inventor	Thomas BETHKE
Art Unit	1616
Examiner Name	SOROUSH, ALI
Attorney Docket Number	27234U

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/A.S./	1	DIETZEL, et al., "Ciclesonide: An On-Site-Activated Steroid", Hansel TT, Barnes PJ (eds): New Drugs for Asthma, Allergy and COPD, Prog Respir Res. Basel, Karger, 2001, vol. 31, pp. 91-93.	
	2	CHAPMAN, et al., "Effects of ciclesonide versus placebo on lung function after 12 weeks of treatment in patients with asthma", Am J Respir Crit Care Med. 2002; 165: Abstract G74, 1 page.	
	3	CHAPMAN, et al., "Effects of ciclesonide versus placebo on lung function after 12 weeks of treatment in patients with asthma", Am J Respir Crit Care Med. 2002; 165: 1 page.	
	4	O'CONNOR, et al., "Management of moderate to severe bronchial asthma by ciclesonide: a 12-week trial", Am J Respir Crit Care Med. 2002; 165: Abstract G75, 1 page.	
	5	O'CONNOR, et al., "Management of moderate to severe bronchial asthma by ciclesonide: a 12-week trial", Am J Respir Crit Care Med. 2002; 165: 1 page.	
	6	PAUWELS, et al., "Effects of inhaled ciclesonide and fluticasone propionate on cortisol secretion and PC ₂₀ for adenosine in asthma patients", Am J Respir Crit Care Med. 2002; 165: Abstract G84, 1 page.	
	7	O'CONNOR, et al., "Treatment of moderate to severe asthma with ciclesonide: a long-term investigation over 52 weeks", Eur Respir J. 2002; 20(suppl 38): Abstract 2579, 1 page.	
	8	ROHATAGI, et al., "Population Pharmacokinetics and Pharmacodynamics of Ciclesonide", J Clin Pharmacol, 2003; 43: pp. 365-378.	
	9	TIMMER, et al., "Repeated inhalation of the new topical steroid ciclesonide does not lead to adrenal suppression in healthy subjects", Am J Respir Crit Care Med. 2000; 161: Abstract A776, 1 page.	
	10	DROLLMANN, et al., "Ciclesonide is effective in the treatment of bronchial asthma", Eur Respir J. 2001; 18: Abstract P681, 1 page.	
▼	11	DROLLMANN, et al., "Ciclesonide is effective in the treatment of bronchial asthma", Eur Respir J. 2001; 18: 1 page.	

Examiner Signature	/Ali Soroush/	Date Considered	01/15/2011
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 3

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First Named Inventor	Thomas BETHKE
Art Unit	1616
Examiner Name	SOROUSH, ALI

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/A.S./	12	WOLTHERS, et al., "Measures of systemic activity of inhaled glucocorticosteroids in children: a comparison of urine cortisol excretion and knemometry", <i>Respiratory Medicine</i> , vol. 89, pp. 347-349, (1995).	
	13	TAYLOR, et al., "A Dose-dependent Effect of the Novel Inhaled Corticosteroid Ciclesonide on Airway Responsiveness to Adenosine-5'-Monophosphate in Asthmatic Patients", <i>Am J Respir Crit Care Med</i> , vol. 160, pp. 237-243, (1999).	
	14	DEROM, et al., "Effects of inhaled ciclesonide and fluticasone propionate on cortisol secretion and airway responsiveness to adenosine 5' monophosphate in asthmatic patients", <i>Pulmonary Pharmacology & Therapeutics</i> , vol. 18, pp. 328-336, (2005).	
	15	GELFAND, et al., "Once-Daily Ciclesonide in Children: Efficacy and Safety in Asthma", <i>J Pediatr</i> , vol. 148, pp. 377-383, (2006).	
	16	POSTMA, et al., "Treatment of asthma by the inhaled corticosteroid ciclesonide given either in the morning or evening", <i>Eur Respir J</i> , vol. 17, pp. 1083-1088, (2001).	
	17	WEINBRENNER, A., et al., "Circadian Rhythm of Serum Cortisol after Repeated Inhalation of the New Topical Steroid Ciclesonide", <i>The Journal of Clinical Endocrinology & Metabolism</i> , vol. 87, no. 5, pp. 2160-2163, (2002).	
	18	AGERTOFT, et al., "Short-term lower-leg growth rate and urine cortisol excretion in children treated with ciclesonide", <i>J Allergy Clin Immunol</i> , vol. 115, pp. 940-945, (2005).	
	19	von BERG, et al., "Comparison of the efficacy and safety of ciclesonide 160 µg once daily vs. budesonide 400 µg once daily in children with asthma", <i>Pediatr Allergy Immunol</i> , vol. 18, pp. 391-400, (2007).	
	20	SKONER, et al., "Assessment of the Long-term Safety of Inhaled Ciclesonide on Growth in Children With Asthma", <i>Pediatrics</i> , vol. 121, no. 1, pp. e1-e14, (2008).	
↓	21	LIPWORTH, et al., "Effect of ciclesonide and fluticasone on hypothalamic-pituitary-adrenal axis function in adults with mild-to-moderate persistent asthma", <i>Ann Allergy Asthma Immunol</i> , vol. 94, pp. 465-472, (2005).	

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/A.S./	22	BOULET, et al., "A randomized study comparing ciclesonide and fluticasone propionate in patients with moderate persistent asthma", Respiratory Medicine, vol. 101, pp. 1677-1686, (2007), Elsevier.	
	23	PEDERSEN, et al., "A Comparative Study of Inhaled Ciclesonide 160 µg/day and Fluticasone Propionate 176 µg/day in Children With Asthma", Pediatric Pulmonology, vol. 41, pp. 954-961, (2006), Wiley-Liss, Inc.	
	24	LEE, et al., "Airway and Systemic Effects of Hydrofluoroalkane Formulations of High-Dose Ciclesonide and Fluticasone in Moderate Persistent Asthma", Chest, vol. 127, pp. 851-860, (2005).	
	25	SZEFLER, et al., "Ciclesonide, a Novel Inhaled Steroid, Does Not Affect Hypothalamic-Pituitary-Adrenal Axis Function in Patients With Moderate-to-Severe Persistent Asthma", Chest, vol. 128, pp. 1104-1114, (2005).	
↓	26	AGERTOFT, et al., "Lower leg growth rates in children with asthma during treatment with ciclesonide and fluticasone propionate", Pediatr Allergy Immunol, pp. 1-7 (2009).	

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